

ODP 0-1038

4 AUG 1980

MEMORANDUM FOR: Executive Officer, DDA

FROM: Bruce T. Johnson
Director of Data Processing

STATINTL

SUBJECT: Proposed Changes [REDACTED]

REFERENCE: Memo fm C/Agency Task Force in
Support of Liaison With the President's
Commission for the Study of Ethical
Problems in Medicine and Biomedical
and Behavioral Research dtd 28 July
1980, same subject, attached to your
note dtd 28 July 80

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The Office of Data Processing concurs in the
amendment to HR [REDACTED] as stated in reference.

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/s/ Bruce T. Johnson

Bruce T. Johnson

O/D/ODP/[REDACTED] ee/8-4-80

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80-0747/9

28 July 1980

MEMORANDUM FOR: Deputy Director for Administration

VIA: Charles A. Bohrer, M.D.
Director of Medical Services

FROM: [REDACTED], M.D.

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Chairman, Agency Task Force in Support of
Liaison With the President's Commission for
the Study of Ethical Problems in Medicine and
Biomedical and Behavioral Research

SUBJECT: Proposed Changes in Headquarters Regulation [REDACTED]

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1. The Agency Task Force has developed proposed amendments to HR [REDACTED] which should bring the Agency into accordance with the requirements of 45 CFR 46 inasmuch as the Agency considers itself to be an institution conducting research on human subjects.

2. The Task Force is of the opinion that the proposed amendments will provide the Agency with a flexible framework within the guidelines issued by the Department of Health and Human Services (formerly the Department of Health, Education and Welfare). As the DDA representative to the Task Force, I am seeking comments and suggestions within the DDA.

3. I suggest that you consider disseminating copies of this document with the attachments to each office head for comment and return to me. Concurrently, a few minutes of discussion at one of the DDA staff meetings in the next week or so would be helpful in raising a general awareness of the necessary safeguards when conducting research on human subjects as well as providing more cogent suggestions for the proposed amendment to the regulation.

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Attachments

- A. HR [REDACTED] (pp 1-7)
- B. Proposed amendment to HR [REDACTED]

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I. RESTRICTIONS ON INTELLIGENCE ACTIVITIES

SYNOPSIS: This regulation implements the provisions of Executive Order 12036 that impose various restrictions on the intelligence activities of the Agency, particularly with regard to activities involving United States persons. The regulation also includes Agency policies regarding, among other things, the conduct of security investigations, relations between the Agency and other governmental entities, and relationships between the Agency and members of the U.S. news media, U.S. clergy, the U.S. academic community, and employees of the Congress.

a. GENERAL

- (1) The intelligence activities of the United States, including the activities of the Agency and the Office of the Director, are restricted by various provisions of law and, in particular, Executive Order 12036 (43 Fed. Reg. 3674, 26 January 1978), particularly Section 2. Provisions of the Executive Order which are quoted in this regulation are indicated by italics. Nothing in these portions of the Executive Order or this regulation is intended to authorize any activity not otherwise authorized or to provide exemption from any more restrictive statute, Presidential directive, Executive order, or regulation. Unless otherwise specified, the provisions of this regulation apply to activities of both the Agency and the Office of the Director whether inside or outside the United States. References to law are to the Constitution and applicable laws of the United States. This regulation will not be amended without the approval of the Director or the Deputy Director of Central Intelligence.
- (2) No activity or action shall be authorized which would intentionally, or reasonably would be expected to, abridge the Constitutional or legal rights of U.S. persons, whether in the United States or abroad.
- (3) To ensure that all activities are in compliance with the law, Deputy Directors and Heads of Independent Offices shall consult with the Office of General Counsel on all activities whose legality is not clearly established. The General Counsel shall have access to all information necessary to perform the duties of that office (see HR [REDACTED]).
- (4) The Inspector General is authorized to review all activities and shall have access to all information necessary to perform the duties of that office (see HR [REDACTED]).
- (5) Any activities or proposed activities that may raise questions of compliance with law, Executive order, or regulation, or that may otherwise appear improper, will be brought directly to the attention of the Director.
- (6) Any employee who has knowledge of past, current, or proposed CIA activities that might be construed to be illegal, improper, questionable, or not authorized by applicable law, Presidential directive, Executive order, or regulation, or who believes that instructions received in any way appear to be illegal, improper, or questionable, shall inform the Director or Inspector General immediately.
- (7) Any employee who, in the course of official duty, becomes aware of any information, allegation, or complaint of possible violations of Federal criminal law by any person, including a person employed by, assigned to, or acting for the Agency, is required to report immediately such information, allegation, or complaint to the General Counsel. The Office of General Counsel shall consult with the Office of Security and the Office of the Inspector General when necessary in conducting a preliminary inquiry to determine whether a basis for referral exists and shall obtain from concerned Agency components an evaluation of the impact, if any, of a prosecution of such a violation on the national security or foreign relations of the United States, including intelligence operations which

— Revised: 21 November 1979 (1262)

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may be jeopardized or intelligence sources and methods which may be compromised. Pursuant to 28 U.S.C. 535 and Section 1-706 of Executive Order 12036, evidence of possible violations of Federal criminal law shall be reported expeditiously to the Attorney General by the General Counsel in accordance with procedures and guidelines adopted by the Attorney General. Cases involving breaches of security shall be reported to the Director of Security, who shall inform the General Counsel of serious or continuing breaches. The General Counsel shall, in compliance with Section 1-707 of Executive Order 12036, recommend to the Attorney General that such cases be referred to the FBI for further investigation. (Required procedures and guidelines will be included as Annex F.)

(S) The provisions of any previously published regulatory issuance inconsistent with the provisions of this regulation are superseded.

b. **DEFINITIONS.** For the purpose of this regulation, and except as may be provided in the annexes to this regulation, the following terms shall have these meanings.

- (1) *"Communications security"* means protective measures taken to deny unauthorized persons information derived from telecommunications of the United States Government related to national security and to ensure the authenticity of such telecommunications.
- (2) *"Counterintelligence"* means information gathered and activities conducted to protect against espionage and other clandestine intelligence activities, sabotage, international terrorist activities or assassinations conducted for or on behalf of foreign powers, organizations or persons, but not including personnel, physical, document, or communications security programs.
- (3) *"Electronic Surveillance"* means acquisition of a nonpublic communication by electronic means without the consent of a person who is a party to an electronic communication or, in the case of a nonelectronic communication, without the consent of a person who is visibly present at the place of communication, but not including the use of radio direction finding equipment solely to determine the location of a transmitter. The monitoring of a telephone conversation with the consent of one party does not constitute electronic surveillance under this definition. This is consistent with Title III of the Omnibus Crime Control and Safe Streets Act of 1968. Also, the recording of an ordinary oral conversation by someone who can be seen by both parties to it, and is in reasonably close proximity to the parties and therefore can reasonably be expected to overhear it, does not constitute electronic surveillance.
- (4) *"Employee"* means persons employed by, assigned to, or acting for the Agency and the Office of the Director, except as otherwise defined in the annexes to this regulation.
- (5) *"Foreign Intelligence"* means information relating to the capabilities, intentions and activities of foreign powers, organizations or persons, but not including counterintelligence except for information on international terrorist activities.
- (6) *"Intelligence"* means foreign intelligence and counterintelligence.
- (7) *"Intelligence Community"* and *"agency"* or *"agencies within the Intelligence Community"* refer to the following organizations:
 - (a) The Central Intelligence Agency (CIA);
 - (b) The National Security Agency (NSA);
 - (c) The Defense Intelligence Agency;
 - (d) The Offices within the Department of Defense for the collection of specialized national foreign intelligence through reconnaissance programs;
 - (e) The Bureau of Intelligence and Research of the Department of State;
 - (f) The intelligence elements of the military services, the Federal Bureau of Investigation (FBI), the Department of the Treasury, the Department of Energy, and the Drug Enforcement Administration (DEA); and
 - (g) The staff elements of the Office of the Director of Central Intelligence (see HR [REDACTED])

- (5) "International terrorist activities" means any activity or activities which:
- (a) involves killing, causing serious bodily harm, kidnapping, or violent destruction of property, or an attempt or credible threat to commit such acts; and
 - (b) appears intended to endanger a protectee of the Secret Service or the Department of State or to further political, social or economic goals by intimidating or coercing a civilian population or any segment thereof, influencing the policy of a government or international organization by intimidation or coercion, or obtaining widespread publicity for a group or its cause; and
 - (c) transcends national boundaries in terms of the means by which it is accomplished, the civilian population, government, or international organization it appears intended to coerce or intimidate, or the locale in which its perpetrators operate or seek asylum.
- (9) "Physical surveillance" means an unconsented, systematic and deliberate observation of a person by any means on a continuing basis, or unconsented acquisition of a nonpublic communication by a person not a party thereto or visibly present thereat through any means not involving electronic surveillance. This definition does not include overhead reconnaissance not directed at specific United States persons. The definition of physical surveillance refers primarily to systematic observation of an individual designed to determine all of his or her regular daily activities. The unconsented acquisition of a nonpublic communication by a person not a party thereto or visibly present thereat refers primarily to a situation where a person hides in a room to overhear what persons in the room are saying.
- (10) "Special activities" means activities conducted abroad in support of national foreign policy objectives which are designed to further official United States programs and policies abroad and which are planned and executed so that the role of the United States Government is not apparent or acknowledged publicly, and functions in support of such activities, but not including diplomatic activity or the collection and production of intelligence or related support functions.
- (11) "United States," when used to describe a place, includes the territories of the United States.
- (12) "United States person" means:
- (a) A citizen of the United States;
 - (b) An alien lawfully admitted for permanent residence;
 - (c) An unincorporated association organized in the United States or substantially composed of United States citizens or aliens lawfully admitted for permanent residence; or
 - (d) A corporation incorporated in the United States.

c. POLICY

(1) RESTRICTIONS ON COLLECTION

(a) General Provisions

- (1) The activities described in paragraphs (b) through (s) below shall be undertaken only as permitted by this regulation and, where required, by procedures established by the Director and approved by the Attorney General. Those procedures shall protect constitutional rights and privacy, ensure that information is gathered by the least intrusive means possible, and limit use of such information to lawful governmental purposes.
- (2) Activities described in paragraphs (b) through (e) for which a warrant would be required if undertaken for law enforcement rather than intelligence purposes shall not be undertaken against a United States person without a judicial

warrant, unless the President has authorized the type of activity involved and the Attorney General has both approved the particular activity and determined that there is probable cause to believe that the United States person is an agent of a foreign power.

- (b) *Electronic Surveillance.* The CIA may not engage in any electronic surveillance within the United States. No agency within the Intelligence Community shall engage in any electronic surveillance directed against a United States person abroad or designed to intercept a communication sent from, or intended for receipt within, the United States, except as permitted by the procedures established pursuant to paragraph c(1)(a). Training of personnel by agencies in the Intelligence Community in the use of electronic communications equipment, testing by such agencies of such equipment, and the use of measures to determine the existence and capability of electronic surveillance equipment being used unlawfully shall not be prohibited and shall also be governed by such procedures. Such activities shall be limited in scope and duration to those necessary to carry out the training, testing or countermeasures purpose. No information derived from communications intercepted in the course of such training, testing or use of countermeasures may be retained or used for any other purpose. (See classified Annex B for required procedures concerning electronic surveillance, and Annex B-1 concerning training and testing in this area, which shall remain in effect until such time as final procedures for electronic surveillance, testing, and audio countermeasures activities are developed under paragraph c(1)(a).) CIA may request other agencies with authority to do so to conduct electronic surveillance within the U.S. for legitimate foreign intelligence or counterintelligence purposes, and CIA may aid such agencies in the conduct of electronic surveillance within the U.S. for foreign intelligence or counterintelligence purposes, through the provision of technical assistance and expert personnel, provided OGC is consulted prior to requesting such surveillance or furnishing such assistance or personnel.
- (c) *Television Cameras and Other Monitoring.* No agency within the Intelligence Community shall use any electronic or mechanical device surreptitiously and continuously to monitor any person within the United States, or any United States person abroad, except as permitted by the procedures established pursuant to paragraph c(1)(a). (Required procedures will be included as Annex C at such time as they have been established and approved.) In the interim, OGC must be consulted prior to initiating any such activity.
- (d) *Unconsented Physical Searches.* No agency within the Intelligence Community except the FBI may conduct any unconsented physical searches within the United States. All such searches conducted by the FBI, as well as all such searches conducted by any agency within the Intelligence Community outside the United States and directed against United States persons, shall be undertaken only as permitted by procedures established pursuant to paragraph c(1)(a). (See classified Annex C for required procedures which shall remain in effect until such time as revised under paragraph c(1)(a). In the interim, OGC must be consulted prior to initiating any such activity.)
- (e) *Mail Surveillance.* No agency within the Intelligence Community shall open mail or examine envelopes in United States postal channels, except in accordance with applicable statutes and regulations. No agency within the Intelligence Community shall open mail of a United States person abroad except as permitted by procedures established pursuant to paragraph c(1)(a). The opening of mail of a U.S. person abroad constitutes an unconsented physical search directed at that person and is limited as in (d) above. To the extent CIA may need mail cover information from within U.S. postal channels in furtherance of its legitimate activities, it shall make

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appropriate requests to the FBI. (Required procedures will be included as Annex H at such time as they have been established and approved. In the interim, OGC must be consulted prior to initiating any such activity.)

- (f) *Physical Surveillance.* The FBI may conduct physical surveillance directed against United States persons or others only in the course of a lawful investigation. Other agencies within the Intelligence Community may not undertake any physical surveillance directed against a United States person unless (see Annex A for required procedures which shall remain in effect until such time as revised under paragraph c(1)(a)).
- (1) *The surveillance is conducted outside the United States and the person being surveilled is reasonably believed to be acting on behalf of a foreign power, engaging in international terrorist activities, or engaging in narcotics production or trafficking; provided, however, that such surveillance directed against U.S. persons reasonably believed to be engaged in international narcotics activities abroad is subject to the limitations set forth in paragraph c(3)(c) below.*
- (2) *The surveillance is conducted solely for the purpose of identifying a person who is in contact with someone who is the subject of a foreign intelligence or counterintelligence investigation; or*
- (3) *That person is being surveilled for the purpose of protecting foreign intelligence and counterintelligence sources and methods from unauthorized disclosure or is the subject of a lawful counterintelligence, personnel, physical or communications security investigation.*
- (4) *No surveillance under paragraph (3) above may be conducted within the United States unless the person being surveilled is a present employee, intelligence agency contractor or employee of such a contractor, or is a military person employed by a non-intelligence element of a military service. Outside the United States such surveillance may also be conducted against a former employee, intelligence agency contractor or employee of a contractor or a civilian person employed by a non-intelligence element of an agency within the Intelligence Community. A person who is in contact with such a present or former employee or contractor may also be surveilled, but only to the extent necessary to identify that person.*
- (g) *Undisclosed Participation in Domestic Organizations.* No employees may join, or otherwise participate in, any organization within the United States on behalf of any agency within the Intelligence Community without disclosing their intelligence affiliation to appropriate officials of the organization, except as permitted by procedures established pursuant to paragraph c(1)(a). (Required procedures will be included as Annex I at such time as they have been established and approved.) Such procedures shall provide for disclosure of such affiliation in all cases unless the agency head or a designee approved by the Attorney General finds that nondisclosure is essential to achieving lawful purposes, and that finding is subject to review by the Attorney General. Those procedures shall further limit undisclosed participation to cases where:
 - (1) *The participation is undertaken on behalf of the FBI in the course of a lawful investigation;*
 - (2) *The organization concerned is composed primarily of individuals who are not United States persons and is reasonably believed to be acting on behalf of a foreign power; or*
 - (3) *The participation is strictly limited in its nature, scope and duration to that necessary for other lawful purposes relating to foreign intelligence and is a type of participation approved by the Attorney General and set forth in a public document. No such participation may be undertaken for the purpose of influencing the activity of the organization or its members.*

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(h) *Collection of Nonpublicly Available Information.* No agency within the Intelligence Community may collect, disseminate or store information concerning the activities of United States persons that is not available publicly, unless it does so with their consent or as permitted by procedures established pursuant to paragraph c(1)(a). The means by which such information is collected must conform to the restrictions stated elsewhere in this regulation and its annexes. (Required procedures will be included as Annex J at such time as they have been established and approved.) Those procedures shall limit collection, storage or dissemination to the following types of information:

- (1) *information concerning corporations or other commercial organizations or activities that constitutes foreign intelligence or counterintelligence;*
- (2) *information arising out of a lawful counterintelligence or personnel, physical or communications security investigation;*
- (3) *information concerning present or former employees, present or former intelligence agency contractors or their present or former employees, or applicants for any such employment or contracting, which is needed to protect foreign intelligence or counterintelligence sources or methods from unauthorized disclosure (see paragraph c(4)(b));*
- (4) *information needed solely to identify individuals in contact with those persons described in paragraph (3) or with someone who is the subject of a lawful foreign intelligence or counterintelligence investigation;*
- (5) *information concerning persons who are reasonably believed to be potential sources or contacts, but only for the purpose of determining the suitability or credibility of such persons;*
- (6) *information constituting foreign intelligence or counterintelligence gathered abroad or from electronic surveillance conducted in compliance with paragraph c(1)(b) or from cooperating sources in the United States;*
- (7) *information about a person who is reasonably believed to be acting on behalf of a foreign power, engaging in international terrorist activities or narcotics production or trafficking, or endangering the safety of a person protected by the United States Secret Service or the Department of State; (This exception is limited by paragraphs c(1)(r) and (s), c(2), c(3)(c), and c(4) of this regulation and the appropriate annexes.)*
- (8) *information acquired by overhead reconnaissance not directed at specific United States persons;*
- (9) *information concerning United States persons abroad that is obtained in response to requests from the Department of State for support of its consular responsibilities relating to the welfare of those persons; or*
- (10) *information concerning persons or activities that pose a clear threat to any facility or personnel of an agency within the Intelligence Community. Such information may be retained only by the agency threatened and, if appropriate, by the United States Secret Service and the FBI.*

(i) *Foreign Intelligence.* CIA is authorized by Section 1-801 of Executive Order 12036 to collect foreign intelligence, including information not otherwise obtainable, within the U.S. in coordination with the FBI as required by procedures established by the Director and approved by the Attorney General. (Required procedures will be included as Annex K at such time as they have been established and approved.)

(j) *Tax Information.* No agency within the Intelligence Community shall examine tax returns or tax information except as permitted by applicable law. All requests for such information will be forwarded to OGC after approval by the appropriate Deputy Director. OGC will process such requests in accordance with the Internal Revenue Code and U.S. Treasury regulations.

(k) *Restrictions on Experimentation.* No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education and Welfare. The subject's informed consent shall be documented as required by those guidelines, and no experiment on a subject who has given informed consent shall be undertaken without the specific approval of the Director.

(h) Not used.

(m) *Restrictions on Contracting.* No agency within the Intelligence Community shall enter into a contract or arrangement for the provision of goods or services with private companies or institutions in the United States unless the agency sponsorship is known to the appropriate officials of the company or institution. In the case of any company or institution other than an academic institution, intelligence agency sponsorship may be concealed where it is determined, pursuant to procedures approved by the Attorney General, that such concealment is necessary to maintain essential cover or proprietary arrangements for authorized intelligence purposes. (Required procedures will be included as Annex L at such time as they have been established and approved.)

(n) *Restrictions on Personnel Assigned to Other Agencies.* An employee detailed to another agency within the federal government shall be responsible to the host agency and shall not report to the parent agency on the affairs of the host agency unless so directed by the host agency. The head of the host agency, and any successor, shall be informed of the employee's relationship with the parent agency. In accordance with HR [REDACTED], CIA personnel assigned to other Government agencies for cover purposes, and liaison officers, are not considered to be "detailed" to the other agency involved.

(o) *Prohibition on Assassination.* No person employed by or acting on behalf of the United States Government shall engage in, or conspire to engage in, assassination.

(p) *Restrictions on Special Activities.* No component of the United States Government except an agency within the Intelligence Community may conduct any special activity. Only CIA (or the military services in wartime) may conduct special activities, except where the President determines, with the advice of the Special Coordination Committee of the National Security Council, that another agency is more likely to achieve a particular objective. Special activities must be approved in accordance with Section 1-302 of Executive Order 12036.

(q) *Restrictions on Indirect Participation in Prohibited Activities.* No agency of the Intelligence Community shall request or otherwise encourage, directly or indirectly, any person, organization, or government agency to undertake activities forbidden by Executive Order 12036 or by applicable law.

(r) *Restrictions on Assistance to Law Enforcement Authorities.* Agencies within the Intelligence Community other than the FBI shall not, except as expressly authorized by law:


(1) Provide services, equipment, personnel or facilities to the Law Enforcement Assistance Administration (or its successor agencies) or to state or local police organizations of the United States; or

(2) Participate in or fund any law enforcement activity within the United States.

(s) *Permissible Assistance to Law Enforcement Authorities.* The restrictions in paragraph (r) shall not preclude:

(1) Cooperation with appropriate law enforcement agencies for the purpose of protecting the personnel and facilities of any agency within the Intelligence Community;

(2) Participation in law enforcement activities, in accordance with law and this regulation, to investigate or prevent clandestine intelligence activities by

 (Amend to include the following Def'n)

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"Institutional Review Board" means a panel, created in accordance with the requirements of 45 CFR 46 by an institution conducting research on human subjects, responsible for determining whether human research subjects will be placed at risk and, if risk is involved, whether:

- (a) The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks; (b) The rights and welfare of any such subjects will be adequately protected; and (c) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of 45 CFR 46.

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"Research on Human Subjects" means a formal investigation, designed to develop or contribute to generalizable knowledge, the subjects of which are persons about whom a scientist conducting research obtains (a) data through intervention or interaction with the person, or (b) identifiable private information. Intervention includes both physical procedures by which data are gathered, and manipulation of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the research scientist and the subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to fall within this definition. Data collection and analysis conducted in the normal course of approved administrative, ^{analytical} or operational actions does not constitute research under this definition.

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(k) Restrictions on Experimentation. No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education and Welfare. The subject's informed consent shall be documented as required by those guidelines.

- (1) All documentation and certification prepared in compliance with DHEW guidelines, codified at 45 CFR 46, shall be evaluated by the Director through the Human Subject Research Review Panel consisting of such officers and employees of the CIA and such experts or consultants engaged for this purpose as the Director determines to be appropriate.
- (2) The Director's evaluation shall take into consideration, among other pertinent factors: (a) The adequacy of the proposed Institutional Review Board in the light of the anticipated scope of the applicant institutions' activities and the type of subject populations likely to be involved, (b) the appropriateness of the proposed initial and continuing review procedures in the light of the probable risks, and (c) the size and complexity of the institution.
- (3) On the basis of his evaluation of documentation submitted in accordance with the requirements of this regulation the Director shall (a) approve, (b) enter into negotiations to develop acceptable documentation,

or (c) disapprove. With respect to approved documentation the Director may determine the period during which approvals remain effective or otherwise condition or restrict his approval.

- (4) The Human Subject Research Review Panel shall prepare and make available necessary materials, including procedural instructions, applicable guidelines, and supplementary information, to assist components in complying with the requirements of this regulation.

**INTERNAL
USE ONLY**

CONFIDENTIAL

SECRET

SUBJECT: (Optional)

Proposed Changes in HR

STATINTL

FROM

EXTENSION NO
STATINTL

M.D.

7756

DATE _____

28 July 1980

TO: (Officer designation, room number, and building)

DATE

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OFFICER'S
INITIALS

COMMENTS (Number each comment to show from whom to whom. Draw a line across column after each comment.)

Director of Medical Services

28 JUL 1980

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FO/DOA

29 July

32 Deputy Director for
Administration 7024

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The next meeting of the Agency Task Force will be held on 6 Aug 80. We would appreciate any response by COB 5 Aug 80

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B. J.